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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,912	11/28/2001	John W. Shultz	PRMG-06684	1565

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MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.N.

Office Action Summary	Application No.	Applicant(s)	
	09/995,912	SHULTZ ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 24-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 24-61 is/are rejected.

7)☒ Claim(s) 43 and 61 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/02, 7/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Prosecution on the merits of this application is reopened on claims 24-61 considered unpatentable for the reasons indicated below:

Status of the Claims

2. Claims 24-61 are under prosecution.

The examiner for this application has changed. Please address future correspondence to Examiner BJ Forman, Art Unit: 1634.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 42-43 and 60-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42 and 60 are each indefinite for the recitation "said RNase comprises angiogenin" because while the specification asserts that angiogenin has RNase activity, it is unclear whether and RNase can comprise angiogenin as claimed.

Claims 43 and 61 each contain the trademark/trade name RNASIN. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second

paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a specific inhibitor and, accordingly, the identification/description is indefinite.

Claims 43 and 61 are each further indefinite for the recitations "said ribonuclease inhibitor" because the recitations lack proper antecedent basis in independent Claims 24 and 44.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 24-28, 35, 38-40, 44-48, 53, 56-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kearney et al (U.S. Patent No. 5,589,335, issued 31 December 1996).

Regarding Claim 24, Kearney et al disclose a method for reducing the activity of an RNase comprising providing a preparation comprising at least one RNA heteropolymer (target RNA and riboprobe) and a sample comprising RNase (RNase A) and mixing under conditions such that RNase activity is reduced (Column 14, lines 40-Column 15, line 26). It is noted that the claims require mixing RNA heteropolymer with an RNase under condition whereby RNase

activity is reduced. Kearny et al clearly discloses this method as evidenced by the data presented in Table 3, Column 15. The claim further recites "diminished relative to the activity of said RNase in the absence of said RNA heteropolymer". However, the claim does not recite a method step of measuring activity with and without the heteropolymer and comparing the results. In contrast, the claim broadly recites that the enzyme activity is "diminished relative" to its activity in other conditions. Kearney et al disclose the method wherein the enzyme's activity is 100% inhibited (Table 3, Column 15). Hence, the activity is relatively diminished as claimed.

Regarding Claim 25-28, Kearney et al disclose the method wherein the activity is relatively diminished 100% (Table 3, Column 15).

Regarding Claim 35, Kearney et al disclose the method wherein one or more hetermopolymers are affixed to a support i.e. captured (Column 14, lines 66-67).

Regarding Claim 38, Kearney et al disclose the method wherein the RNase is RNase A (Column 14, lines 58-65).

Regarding Claim 39, Kearney et al disclose the method wherein said preparation further comprises a ribonuclease inhibitor e.g. GT^3, GT^5, GuSCN (Column 14, lines 40-51).

Regarding Claim 40, Kearney et al disclose the method wherein the RNase is in a cell (e.g. Column 29, lines 1-60).

Regarding Claim 44, Kearney et al disclose a method for reducing the activity of an RNase comprising providing a preparation comprising at least one RNA homopolymer (polyA capture probe) and a sample comprising RNase (RNase A) and mixing under conditions such that RNase activity is reduced (Column 14, lines 40-Column 15, line 26). It is noted that the claims require mixing RNA homopolymer with an RNase under condition whereby RNase activity is reduced. Kearny et al clearly discloses this method as evidenced by the data presented in Table 3, Column 15. The claim further recites "diminished relative to the activity of said RNase in the absence of said RNA homopolymer". However, the claim does not recite a

method step of measuring activity with and without the homopolymer and comparing the results. In contrast, the claim broadly recites that the enzyme activity is "diminished relative" to its activity in other conditions. Kearney et al disclose the method wherein the enzyme's activity is 100% inhibited (Table 3, Column 15). Hence, the activity is relatively diminished as claimed.

Regarding Claim 45-48, Kearney et al disclose the method wherein the activity is relatively diminished 100% (Table 3, Column 15).

Regarding Claim 53, Kearney et al disclose the method wherein one or more homopolymers are affixed to a support (Column 14, lines 66-67).

Regarding Claim 56, Kearney et al disclose the method wherein the RNase is RNase A (Column 14, lines 58-65).

Regarding Claim 57, Kearney et al disclose the method wherein said preparation further comprises a ribonuclease inhibitor e.g. GT^3, GT^5, GuSCN (Column 14, lines 40-51).

Regarding Claim 58, Kearney et al disclose the method wherein the RNase is in a cell (e.g. Column 29, lines 1-60).

7. Claims 24-30, 38, 44-48, 50-52 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarngadharan et al (J. Virology, Sept. 1978, 27(3): 568-575).

Regarding Claim 24, Sarngadharan et al disclose a method for reducing the activity of an RNase comprising providing a preparation comprising an RNA heteropolymer and a sample containing an RNase and mixing the preparation under conditions such that the activity of the RNA is diminished relative to the activity in the absence of the heteropolymer (Fig. 4(A), page 573 and page 572, right column).

Regarding Claims 25-28, Sarngadharan et al disclose the method wherein the activity is reduced at least 90%i.e. at RNA concentration of 2.0μg (Fig. F(A)).

Regarding Claim 29, Sarngadharan et al disclose the method wherein the heteropolymer comprises polyA:polyU (page 572, right column).

Regarding Claim 30, Sarngadharan et al disclose the method wherein the heteropolymer comprises polyC:polyG (page 572, right column and page 573, Fig. 4(C)).

Regarding Claim 38, Sarngadharan et al disclose the method wherein the RNase is RNase H (Abstract).

Regarding Claim 44, Sarngadharan et al disclose a method for reducing the activity of an RNase comprising providing a preparation comprising an RNA homopolymer and a sample containing an RNase and mixing the preparation under conditions such that the activity of the RNA is diminished relative to the activity in the absence of the homopolymer (Fig. 4 & 5, page 573-74 and page 572, right column).

Regarding Claims 45-48, Sarngadharan et al disclose the method wherein the activity is reduced at least 90%i.e. at RNA concentration of 2.0μg (Fig. F(A)).

Regarding Claim 50, Sarngadharan et al disclose the method wherein the homopolymer comprises polyA (page 572, right column).

Regarding Claim 51, Sarngadharan et al disclose the method wherein the homopolymer comprises polyG (page 572, right column and page 573, Fig. 4(C)).

Regarding Claim 52, Sarngadharan et al disclose the method wherein the homopolymer comprises polyC (page 572, right column and page 573, Fig. 4(C)).

Regarding Claim 56, Sarngadharan et al disclose the method wherein the RNase is RNase H (Abstract).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 31-34 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarngadharan et al (J. Virology, Sept. 1978, 27(3): 568-575).

Regarding Claim 31-34 and 49, Sarngadharan et al disclose a method for reducing the activity of an RNase comprising providing a preparation comprising an RNA hetero/homopolymer and a sample containing an RNase and mixing the preparation under conditions such that the activity of the RNA is diminished relative to the activity in the absence of the hetero/homopolymer (Fig. 4(A), page 573 and page 572, right column) wherein RNase activity was reduced using heteropolymer and homopolymers (Fig. 4 & 5). Sarngadharan et al further teach that while different heteropolymers and homopolymer reduced activity differently, each tested reduced RNase activity.

Sarngadharan et al do not specifically teach poly GU; poly CU; poly GI; or poly CI heteropolymers or poly I homopolymers. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that the claimed heteropolymers and homopolyers would have functioned equally to those illustrated based on the teaching of Sarngadharan et al wherein they teach "irrespective of the substrate used for measurement, the enzyme was generally inhibited by a variety of natural and synthetic RNAs (page 563, last paragraph). Hence, one or ordinary skill in the art would have had a reasonable expectation that the claimed polymers would have functioned in an equivalent manner.

The courts have stated with regard to homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904).

10. Claims 39-43 and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarngadharan et al (J. Virology, Sept. 1978, 27(3): 568-575) in view of Balwit (Promega Notes, #56, 1996, page 31-32).

Regarding Claim 39-43 and 57-61, Sarngadharan et al disclose a method for reducing the activity of an RNase comprising providing a preparation comprising an RNA hetero/homopolymer and a sample containing an RNase and mixing the preparation under conditions such that the activity of the RNA is diminished relative to the activity in the absence of the hetero/homopolymer (Fig. 4(A), page 573 and page 572, right column) wherein tumor cells comprise RNase activity but they do not specifically teach their method comprises RNase from a tumor cell, wherein the RNase is angiogenin and further comprising the Rinse inhibitor RNASIN.

However, Balwit teach a similar method comprising RNase from a tumor cell, wherein the RNase is angiogenin and further comprising the Rinse inhibitor RNASIN. Balwit further teach that in the presence of angiogenin and RNASIN provides anti-angiogenin activity whereby neovascularization is reduced and tumor growth is inhibited (page 32).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the RNase inhibition method of Sarngadharan et al by using

RNASIN in preparations comprising tumor cells and angiogenin for the expected benefit of reducing neovascularization and inhibiting tumor growth as taught by Balwit (page 32).

11. Claims 35-37 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarngadharan et al (J. Virology, Sept. 1978, 27(3): 568-575) in view of Kearney et al (U.S. Patent No. 5,589,335, issued 31 December 1996) and Lipshutz et al (U.S. Patent No. 6,013,440, filed 10 March 1997).

Regarding Claims 35-37 and 53-55, Sarngadharan et al disclose a method for reducing the activity of an RNase comprising providing a preparation comprising an RNA hetero/homopolymer and a sample containing an RNase and mixing the preparation under conditions such that the activity of the RNA is diminished relative to the activity in the absence of the hetero/homopolymer (Fig. 4(A), page 573 and page 572, right column) but they do not teach the heteropolymers or homopolymer are attached to a solid support e.g. resin or plastic.

Kearney et al teach a similar method comprising providing a preparation comprising at least one RNA hetero/homopolymer and a sample comprising RNase (RNase A) and mixing under conditions such that RNase activity is reduced (Column 14, lines 40-Column 15, line 26) wherein the hetero/homopolymer is affixed to a solid support (i.e. via capture probe hybridization, Column 14, lines 40-67) and Lipshutz et al teach the preferred material for solid support capture of nucleic acids comprises resin or plastic (Column 10, lines 32-34 and Column 20-24).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the hybridization of Sarngadharan et al by capture of the RNA

polymers as taught by Kearney using the preferred material for solid support capture as taught by Lipshutz et al. One of ordinary skill in the art would have been motivated to combine the teachings based on the preferred solid support material taught by Lipshutz et al (Column 10, lines 32-34 and Column 20-24) and further based on the benefits of capture taught by Kearney et al i.e. for physical separation of captured nucleic acids (Column 7, lines, 29-67).

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
June 13, 2004